

APPENDIX A: 510(k) SUMMARY

Sponsor/Submitter: Acclarent, Inc.
1525-B O'Brien Drive
Menlo Park, California 94025

Contact Person: Keri Yen
Sr. Regulatory Affairs Specialist
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Date of Submission: December 1, 2008

Device Trade Name: Relieva Stratus MicroFlow Spacer

Common Name: Frontal Sinus Spacer

Device Classification: Class I

Regulation Number: 21 CFR 878.4800

Classification Name: Manual surgical instrument for general use

Product Code: KAM

Predicate Device: Sinus Spacer (K072891)

Device Description: The Frontal Sinus Spacer is a device that maintains an opening at the frontal sinus for up to 14 days postoperatively. The subject device can be manually removed during an office follow-up visit at any time.

Indications for Use: The MicroFlow Spacer (Frontal) is indicated for use as a postoperative spacer to maintain an opening to the frontal sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction.

Technological Characteristics: The Frontal Sinus Spacer is designed to be implanted into the frontal sinuses and to maintain its position by a self-retention mechanism.

Performance Data: The Frontal Sinus Spacer met all performance acceptance criteria.

Summary of Substantial Equivalence: The Frontal Sinus Spacer is substantially equivalent to the predicate device as confirmed through relevant performance tests.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Acclarent, Inc.
c/o Ms. Keri Yen
Sr. Regulatory Affairs Specialist
1525-B O'Brien Drive
Menlo Park, CA 94025

JAN 29 2009

Re: K083574

Trade/Device Name: Relieva Stratus MicroFlow Spacer / Frontal Sinus Spacer
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: KAM
Dated: December 1, 2009
Received: December 3, 2009

Dear Ms. Yen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



APPENDIX B: INDICATIONS FOR USE STATEMENT510(k) Number (if known): K083574

Trade Name: Relieva Stratus MicroFlow Spacer

Common Name: Frontal Sinus Spacer

Indications For Use: The MicroFlow Spacer (Frontal) is indicated for use as a postoperative spacer to maintain an opening to the frontal sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel C. Campbell
(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

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(Posted November 13, 2003)